

June 30, 2020

a science group company

Technology Sciences Group Inc.

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Megan P. Priest Regulatory Consultant

CONTAINS CONFIDENTIAL INFORMATION

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U.S. Environmental Protection Agency
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Office of Pesticide Programs
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Arlington, VA 22202

Subject: Cellresin Technologies, LLC CR206, EPA File Symbol 93197-X B670: New Product; No Change in an Established Tolerance Exemption

Dear Mr. Bryceland,

On behalf of Cellresin Technologies, LLC, Technology Sciences Group Inc. is submitting the enclosed application for a new end use product, CR206, EPA File Symbol 93197-X. The proposed end use product contains the active ingredient, 1-Methylcyclopropene and is intended for use as a coated film to extend the life and usefulness of fresh fruits and vegetables. The fruits and vegetables are intended to be treated with CR206 while in shipping containers.

For background purposes, Cellresin Technologies, LLC conducted a pre-submission meeting to discuss the enclosed application with EPA on February 6, 2019. The meeting minutes from the meeting are included with the enclosed application. Please note, 40 CFR § 180.4 states certain substances are exempt from being classified as pesticide chemicals. The exception specifically states the following:

"§ 180.4 Exceptions.

The substances listed in this section are excepted from the definitions of "pesticide chemical" and "pesticide chemical residue" under FFDCA section 201(q)(3) and are therefore exempt from regulation under FFDCA section 402(a)(2)(B) and 408. These substances are subject to regulation by the Food and Drug Administration as food additives under FFDCA section 409.

Inert ingredient information may be entitled to confidential treatment

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(a) Inert ingredients in food packaging treated with a pesticide, when such inert ingredients are the components of the food packaging material (e.g. paper and paperboard, coatings, adhesives, and polymers)."

Based on the above exception, the carrier ingredient in CR206, is exempt from regulation as a pesticide chemical and is thus acceptable for use in CR206 as an inert ingredient. Furthermore, Mr. Kerry Leifer confirmed the above exception covers the proposed food uses for CR206. The EPA meeting minutes have been enclosed for easy reference.

The following documents are included to support this amendment:

- 1. Application Form, EPA Form 8570-1;
- 2. Copy of PRIA Fee Payment Receipt (Pay.gov Tracking ID: 26P1T8A9, Agency Tracking Id: 76002806058)
- 3. Confidential Statement of Formula, EPA Form 8570-4;
- 4. Formulator's Exemption Form, EPA Form 8570-27;
- 5. Certification with Respect to Citation of Data; EPA Form 8570-34;
- 6. Data Matrices (Public and Agency Versions), EPA Form 8570-35;
- 7. Proposed Product Label;
- 8. Transmittal Document;
- 9. Data Volumes:
- 10. EPA Meeting Minutes from February 6, 2019 Meeting.

If you have any questions or need additional information regarding this action, please contact me at (202) 828-8954 or megan.priest@tsgconsulting.com.

Sincerely,

Megan P. Priest

Regulatory Consultant

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